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Filed : **March 26, 2004**

REMARKS

By way of Summary, Claims 1-20 are currently pending. No claim amendments have been made in this paper.

The Examiner rejected Claims 1 and 10 under 35 U.S.C. § 102 as being anticipated by King et al. (U.S. Pat. No. 3,874,388). The Examiner rejected Claims 2-9 and 11-13 under 35 U.S.C. § 103 as being unpatentable over King et al in view of Linden et al (U.S. Pat. No. 5,634,936). Additionally, the Examiner rejected Claims 14-20 under 35 U.S.C. § 103 as being unpatentable over Cragg et al. (U.S. Patent No. 5,868,762) in view of Schweich, Jr. et al. (U.S. Pat. No. 5,961,440). Finally, the Examiner rejected Claims 1-20 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 5,961,440. As further discussed below, Applicants respectfully traverse these rejections.

The present application is directed to methods of closing an opening in a patient. In certain embodiments, the present application relates to methods of preventing passage of embolic materials from a left atrial appendage. The methods may include the steps of positioning a patch across an opening of the left atrial appendage and securing the patch to one or more locations surrounding the opening of the left atrial appendage. The securing step may comprise securing the patch with at least one anchor. In certain other embodiments, the methods include the steps of delivering a plurality of anchors to a location adjacent an opening of the left atrial appendage and delivering the anchors into tissue surrounding the opening of the left atrial appendage. In still other embodiments, the present application relates to a method of closing an opening in a patient. The method of closing an opening in a patient includes the steps of delivering a first and a second tissue engagement structures connected to a suture to the opening, engaging the tissue engagement structures with tissue adjacent the opening, and sliding the first tissue engagement structure relative to the second tissue engagement structure along the suture to close the opening.

In contrast, King et al. discloses a device for closing off a septal defect in the vascular system. King et al. discloses a pair of opposed umbrella-like devices locked together in a face-to-face relationship in opposite sides of the septal defect. In other embodiments, King et al. discloses a single umbrella-like element temporarily held in place by an operative element. King et al. does not disclose or suggest closing off the left atrial appendage. Linden et al. discloses

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a plug for closing a septal defect including a polymeric self-hardening material. The self-hardening material is delivered by a catheter device to the defect and hardened in-situ. Linden does not disclose patching the left atrial appendage, nor does it disclose the application of anchors to the defect.

Cragg et al discloses a suturing device for suturing vascular puncture sites. Cragg et al. discloses a device including a pair of suture anchors attached to a corresponding pair of sutures. The suture anchors are positioned in a vascular wall, and the suturing device is retracted, leaving the sutures trailing from each of the anchors. The free ends of the sutures are then tied together. Cragg et al. does not disclose tissue engagement structures slideable with respect to a suture. Moreover, Cragg et al. does not disclose closing an opening by sliding tissue engagement structures relative to a suture.

Schweich, Jr. et al discloses an apparatus for treating an ailing heart by reducing the wall tension therein. The apparatus may include a tension member for drawing two walls of a heart chamber towards each other. Schweich, Jr. et al. does not disclose or suggest applying the apparatus and method disclosed therein to closing an opening.

Double Patenting Rejection

As an initial matter, Applicants note that U.S. Pat. No. 5,961,440, cited in the double patenting rejection, was not made by Applicants, nor is it assigned to ev3 Sunnyvale, Inc., the assignee of the present application. Therefore, Applicants submit that this rejection relies on an improper reference and should be withdrawn. Applicants thank Examiner for discussing this rejection telephonically on August 12, 2005, and note that in this telephone discussion, Examiner confirmed that the citation of the '440 reference in a double patenting rejection was improper in this instance.

Rejections of Claims 1-13

Claims 1 and 10

Examiner rejected Claims 1 and 10 as anticipated by King et al. However, King et al. does not disclose all of the limitations of Claims 1 and 10. Specifically, Claims 1 and 10 each relate to a method of "preventing passage of embolic material *from a left atrial appendage*."

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Claim 1 recites the steps of “positioning a patch across an opening *of the left atrial appendage*,” and “securing the patch at one or more locations *surrounding the left atrial appendage*.” Claim 10 recites the steps of “delivering a plurality of anchors to a location *adjacent an opening of the left atrial appendage*; and delivering the anchors into tissue surrounding the opening of the *atrial appendage*.” In contrast, King et al. is directed to an apparatus and method for closing off a septal defect or shunt in the intravascular system. King et al., Col. 11, lines 53-56. Therefore, because King et al. fails to disclose each limitation of Claims 1 and 10, Applicants respectfully submit that King et al. does not anticipate Claims 1 and 10.

Claims 2-9 and 11-13

Applicants note that Linden et al., cited by Examiner in combination with King et al. in rejections of Claims 2-9 and 11-13, is also directed solely to closing a septal defect. Linden et al., Col. 3, lines 46-47. More specifically, Linden et al. discloses a polymeric plug for obstructing a septal defect. Col. 4, lines 1-16. Linden et al. does not disclose or suggest obstructing the left atrial appendage as is claimed in the present application. Therefore, the combination of King et al. and Linden et al. does not disclose or suggest all of the limitations of Claims 1 or 10 and likewise does not disclose or suggest all of the limitations of Claims 2-9 and 11-13 which depend therefrom. Moreover, Linden et al. distinguishes its septal defect plug from an “umbrella type device,” thereby teaching away from the combination of Linden et al. with King et al. Col. 12, lines 1-7.

For at least the reasons disclosed above, Applicants respectfully submit that the Examiner’s rejections of Claims 1 and 10 as anticipated by King et al. and Claims 2-9 and 11-13 as unpatentable over King et al. in view of Linden et al. should be withdrawn.

Rejection of Claims 14-20

Claims 14-20 were rejected as being unpatentable over Cragg et al. in view of Schweich, Jr. et al. However, the combination of Cragg et al. with Schweich, Jr. et al. fails to disclose all of the limitations of Claim 14.

Cragg et al. discloses a device for suturing a vascular puncture site. More specifically, Cragg et al. discloses a device that includes a pair of suture anchors and a pair of sutures. One

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suture extends from each suture anchor and is fixed to that anchor. Cragg et al., Col. 4, lines 32-35; Col. 5, lines 7-19. To close a puncture site, the tissue surrounding the sutures is gathered around the puncture site, and free ends of the sutures are tied in a knot. Col. 6, lines 36-42.

Schweich, Jr. et al. was cited by the Examiner “to demonstrate the conventionality of delivering tissue engagement structures via catheter.” Schweich, Jr. et al. discloses a device and method for treating a failing heart by reducing tension in the heart wall. Schweich, Jr. et al., Col. 2, lines 46-49. Schweich, Jr. et al. does not disclose closing an opening or slideable tissue engagement structures.

In contrast, Claim 14 of the present application recites a method of closing an opening in a patient comprising the steps of “providing a first tissue engagement structure and a second tissue engagement structure, each of said tissue engagement structures being connected to a suture, at least one of the tissue engagement structures being *slideable relative to said suture*; . . . and *sliding the first tissue engagement structure relative to the second tissue engagement structure along the suture to close the opening*.” Neither Cragg et al. nor Schweich, Jr. et al. discloses a tissue engagement structure that is slideable with respect to a suture. Likewise, neither reference discloses sliding a tissue engagement structure relative to a suture to close an opening: Cragg et al. discusses closing a vascular puncture by knotting a pair of sutures fixed to a corresponding pair of suture anchors, and Schweich, Jr. et al. does not disclose closing an opening at all.

For at least the reasons discussed above, Applicants respectfully submit that Claim 14 is patentable over the combination of Cragg et al. and Schweich, Jr. et al. Accordingly, Claims 15-20, which depend from Claim 14, are likewise patentable over the cited combination of references. Claims 15-20 also each recites a unique combination of features not taught or suggested by the cited art. Therefore, Applicants request that Examiner withdraw the rejection of Claims 14-20.

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In light of the above discussion, Applicants submit that Claims 1-20 are in condition for allowance. Applicants believe no fees are due with the filing of this paper. However, should any fees be due, please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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